



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Maruyama                      Art Unit: 1623  
Serial No. : 09/963,738                      Examiner: Everett White  
Filing Date: September 26, 2001  
For:                      Base Material for Dry Direct Tableting  
                                Comprising Low-substituted Hydroxypropyl  
                                Cellulose

Assistant Commissioner for Patents  
Washington, D.C. 20231

DECLARATION PURSUANT TO RULE 132

I, Naosuke Maruyama, hereby sincerely and solemnly  
declares that

1. I completed a bachelor course at Nagoya City University in March, 1988, being specialized in biochemical of pharmaceuticals. Since April , 1988, I have been employed by Sin-Etsu Chemical Co., Ltd., assignee of the above-identified application where I have been engaged in research focusing mainly on Pharmaceutical Technology Solid Dosage Forms. The publications include "Dry coating using enteric polymeric powder ", Journal of Powder Technology Japan , 35(1998) 447-450 ; "Dry coating: an innovative enteric coating method using a cellulose derivative" , European Journal of Pharmaceutics and Biopharmaceutics 47 (1999) 51-59. I am an inventor of the above-identified application and I am familiar with the subject matter disclosed in the application as well as the disclosures in the references cited against the claims.

2. In order to further prove the improved properties of the solid preparation of the present invention, the following preparation was produced.

<Comparative Example 2>

A fluidized bed granulator (Maltiplex MP-01, manufactured by Powrex Corp. in Japan) was charged with 66.7 g of erythritol and 133.3 g of low-substituted hydroxypropylcellulose (LH-11, manufactured by Shin-Etsu Chemical Co., Ltd. in Japan) containing 0.25 mole of hydroxypropoxyl substituent group. The granulation was carried out at an air flow of 60 m<sup>3</sup>/hr and at temperatures of 60°C for inhalation of air and 35°C for discharge of air, while spraying 60g of distilled water at the rate of 10 g/min. The granules were dried in a hot-air oven at 80°C. The dried granules which had passed through 80-mesh screen with opening of 177 µm were collected.

The obtained granules were evaluated in the manner described in the specification. The result was as follows.

flowability index: 58

binding power: 188 N

disintegration time: 8.0 min.

3. According to Comparative Example 2, lower flowability index and longer disintegration time were observed in comparison with those of Examples 1 to 4 in Table 1 of the specification. Thus, it is evident that the base material of the present invention gives rises to the unexpected result.

4. I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent resulting therefrom.

Dated: August, 18. 2003

Naosuke Manuyama